Complete Summary

GUIDELINE TITLE

Antithrombotic therapy in valvular heart disease. In: Sixth ACCP Consensus Conference on Antithrombotic Therapy.

BIBLIOGRAPHIC SOURCE(S)

Salem DN, Daudelin HD, Levine HJ, Pauker SG, Eckman MH, Riff J. Antithrombotic therapy in valvular heart disease. Chest 2001 Jan;119(1 Suppl):207S-219S. [151 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Systemic embolism associated with:

- Rheumatic mitral valve disease (mitral stenosis and/or mitral regurgitation)
- Mitral valve prolapse
- Mitral annular calcification and nonrheumatic mitral regurgitation
- Aortic valve and aortic arch disorders
- Patent foramen ovale and atrial septal aneurysm
- Infective endocarditis
- Nonbacterial thrombotic endocarditis
- Withdrawal of anticoagulation therapy prior to surgery

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Pulmonary Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To make recommendations for using antithrombotic drugs for various forms of valvular heart disease in order to prevent systemic embolism.

TARGET POPULATION

Patients (particularly in ambulatory settings) with various forms of valvular heart disease, including:

- Rheumatic mitral valve disease (mitral stenosis and/or mitral regurgitation)
- Mitral valve prolapse
- Mitral annular calcification and nonrheumatic mitral regurgitation
- Aortic valve and aortic arch disorders
- Patent foramen ovale and atrial septal aneurysm
- Infective endocarditis
- Nonbacterial thrombotic endocarditis

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention of Systemic Embolism

1. Pharmacologic Interventions:
    a. Warfarin therapy
    b. Aspirin therapy
    c. Warfarin therapy in combination with aspirin, dipyridamole, ticlopidine, or clopidogrel
    d. Heparin therapy
    e. Withdrawal of anticoagulation therapy prior to surgery
    f. Withholding long-term antithrombotic therapy and long-term warfarin therapy in selected patients
2. Monitoring of international normalized ratio

MAJOR OUTCOMES CONSIDERED

- Efficacy of antithrombotic therapy in preventing systemic embolism
- Risks of adverse events, such as bleeding
- Cost effectiveness of antithrombotic therapy in preventing systemic embolism in target population

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The participants reviewed information from an exhaustive review of the literature.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) (see "Rating Scheme for the Strength of the Recommendations") and the methodologic quality of the underlying evidence (A, B, C+, or C).

Grades of evidence for antithrombotic agents:

1A
Methodological strength of supporting evidence: randomized controlled trials without important limitations

1B
Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

1C+
Methodological strength of supporting evidence: no randomized controlled trials, but randomized controlled trial results can be unequivocally extrapolated; or, overwhelming evidence from observational studies

1C
Methodological strength of supporting evidence: observation studies

2A
Methodological strength of supporting evidence: randomized controlled trials without important limitations

2B
Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

2C
Methodological strength of supporting evidence: observational studies

* Such situations include randomized controlled trials with lack of blinding, and subjective outcomes, in which the risk of bias in measurement of outcomes is high; and randomized controlled trials with large loss to follow-up.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The strength of any recommendation depends on two factors: the trade-off between benefits and risks, and the strength of the methodology that leads to estimates of the treatment effect. The rating scheme used for this guideline captures these factors. The guideline developers grade the trade-off between benefits and risks in two categories: (1) the trade-off is clear enough that most patients, despite differences in values, would make the same choice; and (2) the trade-off is less clear, and each patient's values will likely lead to different choices.

When randomized trials provide precise estimates suggesting large treatment effects, and risks and costs of therapy are small, treatment for average patients with compatible values and preferences can be confidently recommended.

If the balance between benefits and risks is uncertain, methodologically rigorous studies providing grade A evidence and recommendations may still be weak (grade 2). Uncertainty may come from less precise estimates of benefit, harm, or costs, or from small effect sizes.

There is an independent impact of validity/consistency and the balance of positive and negative impacts of treatment on the strength of recommendations. In situations when there is doubt about the value of the trade-off, any recommendation will be weaker, moving from grade 1 to grade 2.

Grade 1 recommendations can only be made when there are precise estimates of both benefit and harm, and the balance between the two clearly favors

recommending or not recommending the intervention for the average patient with compatible values and preferences. Table 2 of the original guideline document summarizes how a number of factors can reduce the strength of a recommendation, moving it from grade 1 to grade 2. Uncertainty about a recommendation to treat may be introduced if the target event that is trying to be prevented is less important (confident recommendations are more likely to be made to prevent death or stroke than asymptomatic deep venous thrombosis); if the magnitude of risk reduction in the overall group is small; if the risk is low in a particular subgroup of patients; if the estimate of the treatment effect, reflected in a wide confidence interval (CI) around the effect, is imprecise; if there is substantial potential harm associated with therapy; or if there is an expectation for a wide divergence in values even among average or typical patients. Higher costs would also lead to weaker recommendations to treat.

The more balanced the trade-off between benefits and risks, the greater the influence of individual patient values in decision making. If they understand the benefits and risks, virtually all patients will take aspirin after myocardial infarction or will comply with prophylaxis to reduce thromboembolism after hip replacement. Thus, one way of thinking about a grade 1 recommendation is that variability in patient values or individual physician values is unlikely to influence treatment choice in average or typical patients.

When the trade-off between benefits and risks is less clear, individual patient values will influence treatment decisions even among patients with average or typical preferences.

Grade 2 recommendations are those in which variation in patient values or individual physician values will often mandate different treatment choices, even among average or typical patients.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) and the methodologic quality of the underlying evidence (A, B, C+, or C) (see "Rating Scheme for the Strength of the Evidence").

Grades of recommendation for antithrombotic agents:

1A
Clarity of risk/benefit: risk/benefit clear
Implications: strong recommendation; can apply to most circumstances, without reservation

1B
Clarity of risk/benefit: risk/benefit clear
Implications: strong recommendation; likely to apply to most patients

1C+
Clarity of risk/benefit: risk/benefit clear
Implications: strong recommendation; can apply to most patients in most circumstances

1C
Clarity of risk/benefit: risk/benefit clear
Implications: intermediate-strength recommendation; may change when stronger evidence available

2A
Clarity of risk/benefit: risk/benefit unclear
Implications: intermediate strength recommendation; best action may differ, depending on circumstances or patients' societal values

2B
Clarity of risk/benefit: risk/benefit unclear
Implications: weak recommendation; alternative approaches likely to be better for some patients under some circumstances

2C
Clarity of risk/benefit: risk/benefit unclear
Implications: very weak recommendation; other alternatives may be equally reasonable

COST ANALYSIS

Mitral Valve Prolapse (MVP)

The dilemma of cost-effective antithrombotic therapy in patients with MVP would best be solved by a reliable means of identifying the small cohort of patients at high risk for thromboembolism. In a retrospective study of 26 patients with MVP, Steele et al. reported that platelet survival time was significantly shortened in all 5 patients with a history of thromboembolism, but this abnormality was also observed in one third of the patients without thromboembolism. Future studies of the clinical and laboratory characteristics of MVP patients may succeed in reducing the fraction of patients at risk.

Withdrawal of Anticoagulation Therapy Prior to Surgery

Patients with valvular heart disease receiving warfarin therapy who require surgical procedures present special problems related to withholding and restarting anticoagulation therapy. The risks of bleeding versus thromboembolism as well as the costs must be carefully balanced. Eckman et al. used decision analysis to examine the cost-effectiveness of varying strategies for treating patients with prosthetic heart valves undergoing noncardiac surgery. These authors concluded the marginal cost of prolonging hospitalization to administer heparin was prohibitively high, except when the patient has "the most thrombogenic of valves."

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The initial guidelines were prepared by the chapter committee (the primary authors) and then reviewed separately by the Committee Co-Chairs and methodology experts and finally by the entire group of Consensus Guideline participants.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Please note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Excerpted by the National Guideline Clearinghouse (NGC):

The grading scheme is defined at the end of the Major Recommendations

1. Rheumatic Mitral Valve Disease (Mitral Stenosis and/or Mitral Regurgitation)

   1.1. The guideline developers recommend the use of long-term warfarin therapy at a target international normalized ratio of 2.5 (range, 2.0 to 3.0) in patients with rheumatic mitral valve disease who have either a history of systemic embolism or who have paroxysmal or chronic atrial fibrillation (grade 1C+).

   1.2. The guideline developers recommend long-term warfarin therapy at a target international normalized ratio of 2.5 (range, 2.0 to 3.0) in patients with rheumatic mitral valve disease and normal sinus rhythm, if the left atrial diameter is greater than 5.5 cm (grade 2C). Furthermore, since it is recognized that the risk of thromboembolism may be substantial in some patients with rheumatic mitral valve disease in normal sinus rhythm, the guideline developers recommend that the decision to use warfarin be adjudicated on the basis of comorbid risk factors, particularly left atrial size, age, and the hemodynamic severity of the lesion (grade 2C).

   1.2.1. If recurrent systemic embolism occurs despite adequate warfarin therapy, the guideline developers recommend that clinicians increase the target international normalized ratio to 3.0 (range, 2.5 to 3.5) or add aspirin (80 to 100 milligrams per day; grade 1C).

   1.2.2. For those patients unable to take aspirin, alternative strategies would be to add dipyridamole, 400 milligrams per day, or add ticlopidine, 250 milligrams by mouth twice per day, or add clopidogrel, 75 milligrams by mouth daily (grade 1C).

2. Mitral Valve Prolapse

   2.1. The guideline developers recommend that clinicians do not give long-term antithrombotic therapy to patients with mitral valve prolapse who have

not experienced systemic embolism, unexplained transient ischemic attacks, or atrial fibrillation (all grade 1C).

2.2. In patients with mitral valve prolapse who have documented but unexplained transient ischemic attacks, the guideline developers recommend long-term, low-dose aspirin therapy (grade 2C). The dose currently recommended is 160 to 325 milligrams per day.

2.3. The guideline developers recommend the substitution of long-term warfarin treatment (international normalized ratio, 2.5; range, 2.0 to 3.0) for aspirin in patients with mitral valve prolapse who have documented systemic embolism (grade 1C), chronic or paroxysmal atrial fibrillation (grade 1A), or recurrent transient ischemic attacks (grade 1C) despite aspirin therapy.

3. Mitral Annular Calcification and Nonrheumatic Mitral Regurgitation

3.1. In patients with mitral annular calcification complicated by systemic embolism, not documented to be calcific embolism, the guideline developers recommend long-term warfarin therapy (target international normalized ratio, 2.5; range, 2.0 to 3.0; grade 2C)

3.2. Patients with mitral annular calcification and associated atrial fibrillation should also be treated with long-term warfarin therapy (target international normalized ratio 2.5; range, 2.0 to 3.0; grade 1C+).

Note: This latter recommendation is based on the high incidence of systemic embolism in older atrial fibrillation patients and the demonstrated efficacy of anticoagulant therapy in patients with atrial fibrillation without rheumatic valve disease.

3.3. The guideline developers recommend that clinicians use long-term anticoagulation therapy for patients with mitral regurgitation who have atrial fibrillation or a history of systemic embolism (grade 1C+).

4. Aortic Valve and Aortic Arch Disorders

4.1. The guideline developers do not recommend that clinicians use long-term warfarin therapy for patients with aortic valve disease unless they have another indication for anticoagulation (grade 2C).

4.2. In patients with mobile aortic atheromas and aortic plaques greater than 4 millimeters as measured by transesophageal echocardiography, the guideline developers recommend that clinicians use warfarin therapy (grade 2C).

5. Patent Foramen Ovale and Atrial Septal Aneurysm

5.1. For patients with unexplained systemic embolism or transient ischemic attacks and demonstrable venous thrombosis or pulmonary embolism and either patent foramen ovale or atrial septal aneurysm, the guideline developers recommend that clinicians treat with long-term warfarin therapy,

unless venous interruption or closure of the patent foramen ovale is considered preferable therapy (grade 1C).

Note: In the case of atrial septal aneurysm, the possibility of both paradoxic embolism and systemic embolism from the arterial side of the aneurysm should be considered in choosing therapy.

6. Infective Endocarditis

6.1. The guideline developers recommend that long-term warfarin therapy be continued when endocarditis occurs in patients with a mechanical prosthetic valve unless there are specific contraindications (grade 2C).

Note: It is to be noted that the risk of intracranial hemorrhage is substantial in patients with infective endocarditis. The indications for anticoagulant therapy when systemic embolism occurs during the course of infective endocarditis involving a native or bioprosthetic heart valve are uncertain. The therapeutic decision should consider comorbid factors, including atrial fibrillation, evidence of left atrial thrombus, evidence and size of valvular vegetations, and particularly the success of antibiotic therapy in controlling the infective endocarditis.

7. Nonbacterial Thrombotic Endocarditis

7.1. For patients with nonbacterial thrombotic endocarditis and systemic or pulmonary emboli, the guideline developers recommend treating with heparin (grade 1C).

7.2. The guideline developers recommend the use of heparin therapy for patients with disseminated cancer or debilitating disease who are found to have aseptic vegetations on echocardiographic study (grade 2C).

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) and the methodologic quality of the underlying evidence (A, B, C+, or C).

Definitions:

Grades of recommendations:

1A

Clarity of risk/benefit: risk/benefit clear
Methodological strength of supporting evidence: randomized controlled trials without important limitations
Implications: strong recommendation; can apply to most circumstances, without reservation

1B

Clarity of risk/benefit: risk/benefit clear
Methodological strength of supporting evidence: randomized controlled trials

with important limitations (inconsistent results, methodologic flaws*)
Implications: strong recommendation; likely to apply to most patients

1C+

Clarity of risk/benefit: risk/benefit clear
Methodological strength of supporting evidence: no randomized controlled trials, but randomized controlled trial results can be unequivocally extrapolated; or, overwhelming evidence from observational studies
Implications: strong recommendation; can apply to most patients in most circumstances

1C

Clarity of risk/benefit: risk/benefit clear
Methodological strength of supporting evidence: observation studies
Implications: intermediate-strength recommendation; may change when stronger evidence available

2A

Clarity of risk/benefit: risk/benefit unclear
Methodological strength of supporting evidence: randomized controlled trials without important limitations
Implications: intermediate strength recommendation; best action may differ, depending on circumstances or patients' societal values

2B

Clarity of risk/benefit: risk/benefit unclear
Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)
Implications: weak recommendation; alternative approaches likely to be better for some patients under some circumstances

2C

Clarity of risk/benefit: risk/benefit unclear
Methodological strength of supporting evidence: observational studies
Implications: very weak recommendation; other alternatives may be equally reasonable

* Such situations include randomized controlled trials with lack of blinding, and subjective outcomes, in which the risk of bias in measurement of outcomes is high; and randomized controlled trials with large loss to follow-up.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (refer to "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of antithrombotic therapy in the various forms of valvular heart disease may reduce the risk of systemic embolism while minimizing cost and the potential for adverse events, such as bleeding.

POTENTIAL HARMS

Antithrombotic therapy, particularly with coumarin derivatives or heparin, carries a substantial risk of hemorrhagic complications; this risk varies with the drug used, the intensity of the anticoagulant effect, and the clinical circumstances in individual patients.

Subgroups Most Likely to be Harmed:

Risks of anticoagulant therapy are greater in patients with endocarditis, pregnancy, and bleeding diatheses.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Interpreting the Recommendations

The authors of these guidelines offer recommendations that should not be construed as dictates by the readers, including clinicians, third-party payers, institutional review committees, and courts. In general, anything other than a 1A recommendation indicates that the chapter authors acknowledge that other interpretations of the evidence and other clinical policies may be reasonable and appropriate. Even grade 1A recommendations will not apply to all circumstances and all patients. For instance, the guideline developers have been conservative in their considerations of cost, and have seldom downgraded recommendations from 1 to 2 on the basis of expense. As a result, in jurisdictions in which resource constraints are severe, alternative allocations may serve the health of the public far more than some of the interventions that the developers designate grade 1A. This will likely be true for all less-industrialized countries. However, a weak recommendation (2C) that reduces resource consumption may be more strongly indicated in less-industrialized countries.

Similarly, following grade 1A recommendations will at times not serve the best interests of patients with atypical values or preferences. For instance, consider patients who find anticoagulant therapy extremely aversive, either because it interferes with their lifestyle (prevents participation in contact sports, for instance) or because of the need for monitoring. For such patients, clinicians may reasonably conclude that following some grade 1A recommendations for anticoagulation will be a mistake. The same may be true for patients with particular comorbidities (such as a recent GI bleed or a balance disorder with repeated falls) or other special circumstances (such as very advanced age).

The guideline developers trust that these observations convey their acknowledgment that no guidelines or recommendations can take into account the often compelling idiosyncrasies of individual clinical circumstances. No clinician and no one charged with evaluating the actions of a clinician should attempt to apply their recommendations in a rote or blanket fashion.

Long-term anticoagulant therapy in a patient with valvular heart disease

The decision to initiate long-term anticoagulant therapy in a patient with valvular heart disease is frequently difficult because of the many variables that influence the risks of thromboembolism and of bleeding in a given individual. The patient's age, the specific valve lesion, the heart rhythm, the duration of the valve disease, a history of thromboembolism, patient attitude and lifestyle, associated diseases, and medications all must be considered. Because the state of such variables may change with time, a proper decision at one time in a patient's life may be inappropriate at another time. In some instances, the literature on a given subject is sparse or contains conflicting data that further confound the issue. Since the database for these guidelines is constantly being modified, particularly as a consequence of new randomized clinical trials, the clinician would do well to review his or her decision at frequent intervals.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Salem DN, Daudelin HD, Levine HJ, Pauker SG, Eckman MH, Riff J. Antithrombotic therapy in valvular heart disease. Chest 2001 Jan;119(1 Suppl):207S-219S. [151 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan

GUIDELINE DEVELOPER(S)

American College of Chest Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

Funding was supplied by DuPont Pharmaceuticals.

GUIDELINE COMMITTEE

American College of Chest Physicians Consensus Panel on Antithrombotic Therapy

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Deeb N. Salem, MD, FCCP, Chair; Denise Hartnett Daudelin, RN, MPH; Herbert J. Levine, MD; Stephen G. Pauker, MD; Mark H. Eckman, MD and Joshua Riff, BSc.

Committee Co-Chairs: James E. Dalen, MD, MPH, FCCP; Jack Hirsh, MD, FCCP.

Participants: Giancarlo Agnelli, MD; Gregory W. Albers, MD; Joseph S. Alpert, MD, FCCP; Pierre Amarenco, MD; Sonia S. Anand, MD; David Anderson, MD; Frederick A. Anderson, PhD; Maureen Andrew, MD; Jack E. Ansell, MD; Peter B. Berger, MD; Edward Bovill, MD; Heiner Bucher, MD, MPH; Henry I. Bussey, PharmD; Christopher P. Cannon, MD; John Cairns, MD; G. Patrick Clagett, MD; Clifford W. Colwell, Jr., MD; Barry S. Coller, MD; Deborah J. Cook, MD, MSc, FCCP; Mark Crowther, MD; Denise Hartnett Daudelin, RN, MPH; Daniel Deykin, MD; J. Donald Easton, MD; Mark H. Eckman, MD; Michael Ezekowitz, MD; Garrett FitzGerald, MD; Valentin Fuster, MD; William Geerts, MD, FCCP; Michael Gent, DSc; Jeffrey S. Ginsberg, MD, FCCP; Steve Goldman, MD; Christopher Granger, MD; Ian A. Greer, MD; Gordon H. Guyatt, MD; Jonathan L. Halperin, MD; Robert A. Harrington, MD; John Heit, MD; Russell D. Hull, MBBS, FCCP; Thomas M. Hyers, MD, FCCP; Mark R. Jackson, MD; Alan K. Jacobson, MD; Roman Jaeschke, MD, MSc, Clive Kearon, MB, PhD, FCCP; J. Ward Kennedy, MD; Seth Landefeld, MD; Mark N. Levine, MD;

Herbert J. Levine, MD; H Daniel Lewis, Jr., MD; A. Michael Lincoff, MD; David Matchar, MD; Kevin M. McIntyre, MD, JD; Thomas W. Meade, DM, Alan D. Michelson, MD; Paul Monagle, MBBS; Timothy A. Morris, MD; E. Magnus Ohman, MD, FCCP; Guy Paiement, MD; Carlo Patrono, MD; Stephen G. Pauker, MD; Palle Petersen, MD, DMSc; Graham Frederick Pineo, MD Leon Poller, DSc, MD; Jeffrey J. Popma, MD; Robert Raschke, MD, MS; Gary Raskob, PhD; Joshua Riff; Gerald Roth, MD; Ralph L. Sacco, MD; Eduardo Salazar, MD; Deeb N. Salem, MD, FCCP; Michel M. Samama, MD; Holger J. Schunemann, MD, MSc; Stephen G. Shaughnessy, PhD; Daniel Singer, MD; Paul D. Stein, MD, FCCP; Victor F. Tapson, MD, FCCP; Philip Teal, MD; Pierre Theroux, MD; Alexander G. G. Turpie, MD; Ted Warkentin, MD; John G. Weg, MD, FCCP; Jeffrey Weitz, MD; H. Brownell Wheeler, MD.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Please note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies of the updated guideline: Available from the Chest - The Cardiopulmonary and Critical Care Journal Web site.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Sixth ACCP Consensus Conference on Antithrombotic Therapy (2001): quick reference guide for clinicians. Northbrook, IL: ACCP, 2001.

Electronic copies: Available in from the American College of Chest Physicians Web site. (Downloadable files intended for use with Palm OS compatible devices are available.)

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348, or by calling 1 (800) 343-2227.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on July 30, 2001. The information was verified by the guideline developer on October 31, 2001.

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